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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,302

02/23/2006

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/569,302	Applicant(s) KAUFMAN ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-11,18,19 and 21-41 is/are rejected.
- 7) ☒ Claim(s) 2,4,12-17 and 20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-41 are pending in the application.

Specification

2. This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21-30 and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation

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necessary, the amount of direction or guidance provided, presence of working examples, state of the prior art, unpredictability and the breadth of claims.

The specification mentions on page 1 that the instant compounds are tissue-selective androgen receptor modulators. The specification mentions various assays on pages 88-95. However, there is no teaching or guidance present in the specification regarding agonist versus antagonist activity at androgen receptors in specific tissues of instant compounds. There is no teaching in the specification regarding specific disease conditions whose etiology is well known in the prior art to involve hyperactivity or hypoactivity of androgen receptors. There is no teaching either in the specification or prior art references provided to show that structurally closely related compounds are known in the prior art to have both agonistic and antagonistic effect on androgen receptors in different tissues following their in vivo administration. There is no teaching in the specification or prior art regarding well known utility of structurally closely related compounds in any disease condition listed in instant claims 21-26, 34-37, 40 and 41. There are no working examples present showing efficacy of instant compounds either alone or in combination with hundreds of thousands of drugs listed in instant claims 27-30, 32 and 33 in known animal models of any disease condition. The instant compounds of formula I encompasses several hundreds of thousands of compounds based on the values of variables R1, R2, n, Y, Z, U, V, W, D and X and therefore, in absence of such teachings, guidance, presence of working examples and the state of the prior art, it would require undue experimentation to demonstrate the efficacy of instant compounds alone and/or in combination with thousands of other drugs listed in

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instant claims 27-30, 32 and 33 in animal models of numerous disease conditions listed in instant claims 21-26, 34-37, 40 and 41 and hence their utility for treating these disease conditions.

In regard to inhibiting or preventing any disease condition, it is well known in the art that there are multiple mechanisms involved in the etiology of any known disease condition. Therefore, correcting only one of these several possible mechanisms (agonism or antagonism at androgen receptor in the instant case) will not prevent (completely inhibit or cure) that specific disease condition.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-11, 18, 19 and 21-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmusson (J. Med. Chem., cited on applicant's form 1449).

Rasmusson discloses Azasteroids having binding affinity to androgen receptors. The compounds, 10ap and 10aq (see table II on page 2300) disclosed by Rasmusson anticipate the instant claims when a and b represent a single bond, X, Y, Z, V and W all represent hydrogen, R1 represents an alkyl group, U represents N and D represents either O or S in the instant compounds of formula I. It is of note that both O and S belong to the same class of chalcogens.

Allowable Subject Matter

6. Claims 2, 4, 12-17 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625

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